



Commonwealth of Massachusetts
Executive Office of Energy & Environmental Affairs

Department of Environmental Protection

DEVAL L. PATRICK
Governor

RICHARD K. SULLIVAN JR.
Secretary

KENNETH L. KIMMELL
Commissioner

Date Stamped June 13, 2013

Mr. Anuj Mohan
ChemGenes Corporation
33 Industrial Way
Wilmington, Massachusetts 01887

RE: WILMINGTON
Transmittal No.: X240016
Application No.: *MBR-11-IND-021*
Class: *SUBMIN*
FMF No.: 387392
**AIR QUALITY PLAN
APPROVAL**

Dear Mr. Mohan:

The Massachusetts Department of Environmental Protection ("MassDEP"), Bureau of Waste Prevention, has reviewed your Limited Plan Application ("Application") listed above. This Application concerns your proposal to establish facility-wide process emission limits at your existing facility located at 33 Industrial Way in Wilmington, Massachusetts ("Facility").

This Application was submitted in accordance with 310 CMR 7.02 Plan Approval and Emission Limitations as contained in 310 CMR 7.00 "Air Pollution Control," regulations adopted by MassDEP pursuant to the authority granted by Massachusetts General Laws, Chapter 111, Section 142 A-J, Chapter 21C, Section 4 and 6, and Chapter 21E, Section 6. MassDEP's review of your Application has been limited to air pollution control regulation compliance and does not relieve you of the obligation to comply with any other regulatory requirements.

MassDEP has determined that the Application is administratively and technically complete and that the Application is in conformance with the Air Pollution Control regulations and current air pollution control engineering practice, and hereby grants this **Plan Approval** for said Application, as submitted, subject to the conditions listed below.

Please review the entire Plan Approval, as it stipulates the conditions with which the Facility owner / operator ("Permittee") must comply in order for the Facility to be operated in compliance with this Plan Approval.

1. DESCRIPTION OF FACILITY AND APPLICATION

ChemGenes Corporation is a biotechnology company that manufactures ribonucleic acid (RNA) and deoxyribonucleic acid (DNA) intermediate products at its existing Wilmington, Massachusetts Facility. The Facility utilizes various volatile organic compounds (VOCs) and hazardous air pollutants (HAPs). Although most of the material used is contained within fully or partially closed-loop systems, some of the processes have fugitive and stack emissions.

The process operations at the Facility can be categorized into one of three emission unit categories. Emission Unit No. 1 (EU 01) involves general chemical processing (i.e. small scale reactions/flasks, testing, workup, etc.), mixing, and purification techniques other than column chromatography. EU 02 consists of gravity based separations using column chromatography. EU 03 involves solvent evaporation and drying processes to manufacture its products. EU 04 will consist of a TechnoClean F-2500 25-gallon solvent recycler or equivalent, which will utilize fractional distillation and an air cooled condenser to reclaim high purity solvents for reuse.

2. EMISSION UNIT (EU) IDENTIFICATION

Each Emission Unit (EU) identified in Table 1 is subject to and regulated by this Plan Approval:

Table 1		
EU#	Description	Pollution Control Device (PCD)
EU 01	General Chemical Processing (small scale reactions/flasks, testing, workup, etc.), mixing, and purification techniques other than column chromatography.	None
EU 02	Column chromatography (gravity based separations)	
EU 03	Solvent evaporation/drying operations	
EU 04	Solvent Recycling (fractional distillation)	Self-contained air cooled condenser

Table 1 Key:
EU = Emission Unit
= Number

3. APPLICABLE REQUIREMENTS

A. OPERATIONAL, PRODUCTION AND EMISSION LIMITS

The Permittee is subject to, and shall not exceed the Operational, Production, and Emission Limits as contained in Table 2, below:

Table 2			
EU#	Operational / Production Limit	Air Contaminant	Emission Limit
EU 01	N/A	VOC	0.08 TPM 1.0 TPY
		Total HAPs	0.08 TPM 1.0 TPY
EU 02		VOC	0.08 TPM 1.0 TPY
		Total HAPs	0.08 TPM 1.0 TPY
EU 03		VOC	0.08 TPM 1.0 TPY
		Total HAPs	0.08 TPM 1.0 TPY
EU 04		VOC	0.08 TPM 1.0 TPY
		Total HAPs	0.08 TPM 1.0 TPY
Facility-wide		VOC	0.32 TPM 4.0 TPY
		Total HAPs	0.32 TPM 4.0 TPY

Table 2 Key:

EU# = Emission Unit Number

VOC = Volatile Organic Compounds

Total HAPs = total Hazardous Air Pollutants

TPM = tons per month

TPY = tons per any consecutive 12-month period

N/A = Not Applicable

B. COMPLIANCE DEMONSTRATION

The Permittee is subject to, and shall comply with, the monitoring, testing, record keeping, and reporting requirements as contained in Tables 3, 4, and 5 below:

Table 3	
EU#	Monitoring and Testing Requirements
EU 01, EU 02, EU 03, EU 04	1. Monitor material usage (including VOC and HAPs content) on a monthly basis such that records can be maintained of the Facility's emissions of VOC and total HAPs to determine compliance status with the emission limits contained in Table 2 above.
Facility-wide	2. If and when MassDEP requires it, the Permittee shall conduct emission testing in accordance with USEPA Reference Test Methods and Regulation 310 CMR 7.13.

Table 3 Key:

EU# = Emission Unit Number

VOC = Volatile Organic Compounds

HAPs (total) = total Hazardous Air Pollutants

MassDEP = Massachusetts Department of Environmental Protection

USEPA = United States Environmental Protection Agency

Table 4	
EU#	Record Keeping Requirements
Facility-wide	1. The Permittee shall maintain adequate records on-site to demonstrate compliance with all operational, production, and emission limits contained in Table 2 above. Records shall also include the actual emissions of air contaminant(s) emitted for each calendar month and for each consecutive twelve month period (current month plus prior eleven months). These records shall be compiled no later than the 15 th day following each month. An electronic version of the MassDEP approved record keeping form, in Microsoft Excel format, can be downloaded at http://www.mass.gov/dep/air/approvals/aqforms.htm#report .
	2. The Permittee shall maintain records of monitoring and testing as required by Table 3.
	3. The Permittee shall maintain a copy of this Plan Approval, underlying Application and the most up-to-date SOMP for the EUs approved herein on-site.
	4. The Permittee shall maintain a record of routine maintenance activities performed on the approved EUs and monitoring equipment. The records shall include, at a minimum, the type or a description of the maintenance performed and the date and time the work was completed.

Table 4	
EU#	Record Keeping Requirements
Facility-wide	5. The Permittee shall maintain a record of all malfunctions affecting air contaminant emission rates of the approved EUs and monitoring equipment. At a minimum, the records shall include: date and time the malfunction occurred; description of the malfunction; corrective actions taken; the date and time corrective actions were initiated and completed; and the date and time emission rates and monitoring equipment returned to compliant operation.
	6. The Permittee shall maintain records required by this Plan Approval on-site for a minimum of five (5) years.
	7. The Permittee shall make records required by this Plan Approval available to MassDEP and USEPA personnel upon request.

Table 4 Key:

EU# = Emission Unit Number

EUs = emission units

SOMPs = Standard Operating and Maintenance Procedures

MassDEP = Massachusetts Department of Environmental Protection

USEPA = United States Environmental Protection Agency

Table 5	
EU#	Reporting Requirements
Facility-wide	1. The Permittee shall submit to MassDEP all information required by this Plan Approval over the signature of a "Responsible Official" as defined in 310 CMR 7.00 and shall include the Certification statement as provided in 310 CMR 7.01(2)(c).
	2. The Permittee shall notify the Northeast Regional Office of MassDEP, BWP Permit Chief by email at nero.air@state.ma.us or fax 978-694-3499 as soon as possible, but no later than one (1) business day after discovery of any exceedance(s) of Table 2 requirement(s). A written report shall be submitted to the BWP Permit Chief within three (3) business days thereafter and shall include: identification of exceedance(s), duration of exceedance(s), reason for the exceedance(s), corrective actions taken, and action plan to prevent future exceedance(s).
	3. The Permittee shall provide a copy to MassDEP of any record required to be maintained by this Plan Approval within 30 days from MassDEP's request.
	4. The Permittee shall submit to MassDEP for approval a stack emission pretest protocol, at least 60 days prior to emission testing, for any emission testing as defined in Table 3 Monitoring and Testing Requirements.
	5. The Permittee shall submit to MassDEP a final stack emission test results report, within 45 days after emission testing, for any emission testing as defined in Table 3 Monitoring and Testing Requirements.

Table 5 Key:

EU# = Emission Unit Number

CMR = Code of Massachusetts Regulations

MassDEP = Massachusetts Department of Environmental Protection

BWP = Bureau of Waste Prevention

3. SPECIAL TERMS AND CONDITIONS

The Permittee is subject to, and shall comply with, the following special terms and conditions:

- A. The Permittee shall comply with the Special Terms and Conditions as contained in Table 6 below:

Table 6	
EU#	Special Terms and Conditions
EU 01, EU 02, EU 03, EU 04	1. The Permittee shall follow the Standard Operating and Maintenance Procedures (SOMPs) for the subject emission units so as to maintain their efficient operation and minimize emissions of VOC and total HAPs.
Facility- wide	2. All cleaning rags used in conjunction with cleaning solutions shall be placed in tightly covered containers when not in use, and shall be collected for proper recycling or disposal.
	3. All VOC and/or HAPs containing materials, such as solvents, inks, and clean-up solutions, shall be transported and stored in tightly covered containers. Any emissions associated with surface preparation and /or cleanup solutions shall be included in the monthly and 12 month rolling emissions calculations to determine the Permittee's compliance status with emission limits contained in Table 2 above.
	4. The Permittee shall maintain an Environmental Logbook, or similar record keeping system, which shall document all actions associated with environmental issues and overall emissions changes at the Facility. The Permittee shall record information such as the result of federal, state, or local environmental inspections, and maintenance or corrective actions related to manufacturing. This Logbook, or similar, shall be made available to MassDEP personnel upon request.

Table 6 Key:

EU# = Emission Unit Number

- B. The Permittee shall install and utilize exhaust stacks, as required in Table 7, for EU 01 through EU 03, that are consistent with good air pollution control engineering practice and that discharge so as to not cause or contribute to a condition of air pollution. The subject emission units shall utilize exhaust stacks with the following minimum parameters, as contained in Table 7 below:

Table 7				
EU#	Stack Height Above Roof	Stack Inside Exit Dimensions	Stack Gas Exit Velocity	Stack Gas Exit Temperature Range
EU 01	12 feet	12 inch diameter	44 feet per second	60 °F – 80 °F
EU 02	12 feet	12 inch diameter	44 feet per second	60 °F – 80 °F
EU 03	12 feet	12 inch diameter	44 feet per second	60 °F – 80 °F

Table 7 Note: EU 04 does not have an active stack; however, in an emergency, a pressure relief valve will vent to atmosphere.

Table 7 Key:

EU# = Emission Unit Number

°F = Degrees Fahrenheit

6. GENERAL CONDITIONS

The Permittee is subject to, and shall comply with, the following general conditions:

- A. Pursuant to 310 CMR 7.01, 7.02, 7.09 and 7.10, should any nuisance condition(s), including but not limited to smoke, dust, odor or noise, occur as the result of the operation of the Facility, then the Permittee shall immediately take appropriate steps including shutdown, if necessary, to abate said nuisance condition(s).
- B. If asbestos remediation/removal will occur as a result of the approved construction, reconstruction, or alteration of this Facility, the Permittee shall ensure that all removal/remediation of asbestos shall be done in accordance with 310 CMR 7.15 in its entirety and 310 CMR 4.00.
- C. If construction or demolition of an industrial, commercial or institutional building will occur as a result of the approved construction, reconstruction, or alteration of this Facility, the Permittee shall ensure that said construction or demolition shall be done in accordance with 310 CMR 7.09(2) and 310 CMR 4.00.

- D. Pursuant to 310 CMR 7.01(2)(b) and 7.02(7)(b), the Permittee shall allow MassDEP and/or USEPA personnel access to the Facility, buildings, and all pertinent records for the purpose of making inspections and surveys, collecting samples, obtaining data, and reviewing records.
- E. This Plan Approval does not negate the responsibility of the Permittee to comply with any other applicable Federal, State, or local regulations now or in the future.
- F. Should there be any differences between the Application and this Plan Approval, the Plan Approval shall govern.
- G. Pursuant to 310 CMR 7.02(3)(k), MassDEP may revoke this Plan Approval if the construction work is not commenced within two years from the date of issuance of this Plan Approval, or if the construction work is suspended for one year or more.
- H. This Plan Approval may be suspended, modified, or revoked by MassDEP if MassDEP determines that any condition or part of this Plan Approval is being violated.
- I. This Plan Approval may be modified or amended when in the opinion of MassDEP such is necessary or appropriate to clarify the Plan Approval conditions or after consideration of a written request by the Permittee to amend the Plan Approval conditions.
- J. The Permittee shall conduct emission testing, if requested by MassDEP, in accordance with USEPA Reference Test Methods and regulation 310 CMR 7.13. If required, a pretest protocol report shall be submitted to MassDEP at least 30 days prior to emission testing and the final test results report shall be submitted within 45 days after emission testing.
- K. Pursuant to 310 CMR 7.01(3) and 7.02(3)(f), the Permittee shall comply with all conditions contained in this Plan Approval. Should there be any differences between provisions contained in the General Conditions and provisions contained elsewhere in the Plan Approval, the latter shall govern.

7. MASSACHUSETTS ENVIRONMENTAL POLICY ACT

MassDEP has determined that the filing of an Environmental Notification Form (ENF) with the Secretary of Energy & Environmental Affairs, for air quality control purposes, was not required prior to this action by MassDEP. Notwithstanding this determination, the Massachusetts Environmental Policy Act (MEPA) and 301 CMR 11.00, Section 11.04, provide certain “Fail-Safe Provisions,” which allow the Secretary to require the filing of an ENF and/or an Environmental Impact Report (EIR) at a later time.

8. APPEAL PROCESS

This Plan Approval is an action of MassDEP. If you are aggrieved by this action, you may request an adjudicatory hearing. A request for a hearing must be made in writing and postmarked within twenty-one (21) days of the date of issuance of this Plan Approval.

Under 310 CMR 1.01(6)(b), the request must state clearly and concisely the facts, which are the grounds for the request, and the relief sought. Additionally, the request must state why the Plan Approval is not consistent with applicable laws and regulations.

The hearing request along with a valid check payable to the Commonwealth of Massachusetts in the amount of one hundred dollars (\$100.00) must be mailed to:

Commonwealth of Massachusetts
Department of Environmental Protection
P.O. Box 4062
Boston, MA 02211

This request will be dismissed if the filing fee is not paid, unless the appellant is exempt or granted a waiver as described below. The filing fee is not required if the appellant is a city or town (or municipal agency), county, or district of the Commonwealth of Massachusetts, or a municipal housing authority.

MassDEP may waive the adjudicatory hearing-filing fee for a person who shows that paying the fee will create an undue financial hardship. A person seeking a waiver must file, together with the hearing request as provided above, an affidavit setting forth the facts believed to support the claim of undue financial hardship.

Should you have any questions concerning this Plan Approval, please contact Mr. Mun Wong by telephone at 978-694-3286, or in writing at the letterhead address.

This final document copy is being provided to you electronically by the Department of Environmental Protection. A signed copy of this document is on file at the DEP office listed on the letterhead.

Mun S. Wong
Environmental Engineer

Sincerely,

This final document copy is being provided to you electronically by the Department of Environmental Protection. A signed copy of this document is on file at the DEP office listed on the letterhead.

James E. Belsky
Permit Chief
Bureau of Waste Prevention

ecc: Board of Health, 121 Glen Road, Wilmington MA 01887
Fire Headquarters, 1 Adelaide Street, Wilmington MA 01887
MassDEP/Boston - Yi Tian
MassDEP/NERO – Marc Altobelli, M. Persky